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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,597	03/05/1999	WILLIAM BUTLER COWDEN	120081.403	2400

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	23

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/142,597	Applicant(s) Cowden et al.
	Examiner S. Devi, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 2, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, 4, and 6-8* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, 4 and 6-8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 04/03/03 (paper no. 22) in response to the non-final Office Action mailed 01/02/03 (paper no. 21).

Status of Claims

2) Claims 3, 15-17 and 19-21 have been canceled via the amendment filed 04/03/03.

Claims 1 has been amended via the amendment filed 04/03/03.

Claims 1, 2, 4 and 6-8 are pending and are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

5) The rejection of claim 15 made in paragraph 11(c) of the Office Action mailed 04/03/03 (paper no. 22) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

6) The rejection of claims 3, 16, 17 and 19-21 made in paragraph 11(d) of the Office Action mailed 04/03/03 (paper no. 22) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

7) The rejection of claims 15-17 and 19-21 made in paragraph 12 of the Office Action mailed 04/03/03 (paper no. 22) under 35 U.S.C § 102(b) as being anticipated by Zhang *et al.* (*Acta Virologica* 38: 327-332, 1994, already of record), or Gajdosova *et al.* (*Acta Virologica* 38: 339-344, 1994, already of record) or Vodkin *et al.* (*J. Bacteriol.* 170: 1227-1234, 1988, already of record), or Williams *et al.* (*Infect. Immun.* 51: 851-858, 1986, already of record), is moot in light of Applicants' cancellation of the claims.

8) The rejection of claim 3 made in paragraph 7 of the Office Action mailed 06/21/00 (paper no.

7) and maintained in paragraph 12 of the Office Action mailed 03/21/01 (paper no. 10), paragraph 7 of the Office Action mailed 04/10/02 (paper no. 18) and paragraph 10 of the Office Action mailed 04/03/03 (paper no. 22) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of Applicants' cancellation of the claim.

Rejection(s) Maintained

9) The rejection of claims 1, 2, 4 and 6-8 made in paragraph 7 of the Office Action mailed 06/21/00 (paper no. 7) and maintained in paragraph 12 of the Office Action mailed 03/21/01 (paper no. 10), paragraph 7 of the Office Action mailed 04/10/02 (paper no. 18) and paragraph 10 of the Office Action mailed 04/03/03 (paper no. 22) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is maintained for reasons set forth therein and herebelow.

Applicants submit that the mere presence of some inoperative embodiments within the scope of a claim does not render a claim non-enabled, and that one of skill in the art could determine which embodiments would be inoperative, without undue experimentation, given the teachings in Examples 1-5. Applicants contend that claim 1 recites a functional limitation, 'effective amount', which would exclude inoperative embodiments. Applicants state that the Cowden Declaration demonstrates how to distinguish active components of *C. burnetii* from an inactive fraction by way of DMSO extraction.

Applicants' arguments have been carefully considered, but are non-persuasive. The phrase that is at issue is: "one or more antigenic components". The term 'effective amount' does not provide for the unfounded breadth of the phrase 'one or more antigenic components'. The purpose behind section 112 is that the *invention claimed* should be no broader than the *invention set forth* in the written description contained in the specification. The examples and other exemplary material used in the disclosure to support a claim must be adequately representative of the area covered by it. Examples 1-5 of the instant specification describe how art-known or art-available QFA and QVAX antigens of *Coxiella burnetii* are used in the claimed method. These two art-known antigen species do not provide for the broadly recited genus, 'one or more antigenic components'. As set forth previously, one skilled in the art would learn from the instant specification that certain isolated antigenic components of *Coxiella burnetii*, such as, the QFA and QVAX would be suitable for the purposes of the invention, but any antigenic component(s), as claimed, would not be so suitable. The

Cowden Declaration describes the CMR residue and the DMSO extract or the delipidated extract of *Coxiella burnetii* as suitable for the purposes of the invention. These antigenic components were not described or contemplated in the specification, as originally filed. The specification has further explicitly demonstrated that a CME component and the LPS antigenic components of *Coxiella burnetii* did **not** exert a therapeutic or prophylactic effect against IDDM. Other antigenic components of *C. burnetii* such as "membrane/wall preparation" and an "endospore preparation" of a *Coxiella* species (let alone of *C. burnetii*) are merely mentioned on page 6 of the specification and have not been demonstrated to be of therapeutic or prophylactic significance in mammals with IDDM. Their therapeutic or prophylactic role against IDDM is purely speculative. The recited phrase 'one or more antigenic components' is so broad that it embraces subject matter not described to be Applicants' actual invention by means of adequate representative examples. *In re Lund, 54 CCPA 1361, 376 F.2d 982, 153 USPQ 625 (1967)*; *In re Holmen, 52 CCPA 1626, 347 F.2d 852, 146 USPQ 290*. For example, the phrase 'one or more antigenic components' encompasses isolated or non-isolated, intracellular or extracellular, purified, semi-purified or non-purified, lipidated or delilipidated, DMSO-extracted or DMSO non-extracted, enzymatically treated or enzymatically untreated, lysozyme-treated or lysozyme non-treated, toxic or non-toxic, pathologic or non-pathologic antigenic components of *C. burnetii*. As set forth previously, although one of skill in the art may be able to produce several antigenic components of *C. burnetii*, one cannot predict that any "one or more antigenic components of *C. burnetii*" would be prophylactic or therapeutic against IDDM and are usable in the claimed method. Furthermore, the disclosure within the instant specification as well as the data provided in the Cowden Declaration clearly establish that one of skill in the art cannot extrapolate the IDDM-delaying effect of one antigenic component of *C. burnetii*, such as the QFA or the QVAX extract, to another antigenic component of *C. burnetii*, such as the CME component or the LPS fraction. It does not appear that Applicants were in possession of the CME residue and the DMSO extract of *C. burnetii* which were prophylactically or therapeutically functional against IDDM, at the time of the invention. A myriad of antigenic components of non-infectious *Coxiella burnetii* that are therapeutically or prophylactically inoperative against IDDM, some with the demonstrated non-therapeutic or non-prophylactic effect against IDDM, and those whose operability is merely speculated, are currently encompassed in the scope of the method claims.

Regardless of the complexity or simplicity of the method of isolation of antigenic components, conception cannot be achieved until reduction to practice has occurred. The provision of 35 U.S.C § 112, first paragraph, requires more than a mere statement that its is a part of the invention and a reference to a potential method of isolating such components. In view of the therapeutic or prophylactic unpredictability demonstrated within the instant specification, one of ordinary skill would be forced into experimentation that is undue. The courts have held that it is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. See *Genentech Inc., v. Novo Nordisk A/S Ltd., 42 USPQ d 1001*. Moreover, the specification must have been enabling at the time the invention was made and developments after the time of filing are of no consequence to what one skilled in the art would have believed at the time of filing (*In re Wright, 27 USPQ2d 1510, Federal Circuit, 1993*). Given the therapeutic or prophylactic unpredictability associated with several antigenic components of *C. burnetii*, and the broad scope of protection sought in the claims, one skilled in the art would be forced into experimentation that is undue. Clearly, the claims fail to meet the requirements of 35 U.S.C § 112, first paragraph, in that they are broader than the invention described in the specification. *In re Sus 49 CCPA 1301, 306 F.2d 494, 134 USPQ 301*; and *In re Holmen, 52 CCPA 1626, 347 F.2d 852, 146 USPQ 290*. The rejection stands.

Rejection(s) Withdrawn

10) The rejection of 1 made in paragraphs 11(a), 11(b) and 11(c) of the Office Action mailed 04/03/03 (paper no. 22) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claims 2 and 6-8 made in paragraph 11(d) of the Office Action mailed 04/03/03 (paper no. 22) under 35 U.S.C § 112, second paragraph, as being, is maintained for reasons set forth therein and herebelow.

Remarks

12) Claims 1, 2, 4 and 6-8 stand rejected.

In is suggested that, for proper antecedence, Applicants replace the recitation "A method according to claim ..." in claims 2, 4, 6, 7 and 8 with --The method of according to claim .....--.

13) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office

action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER